

## SENATE BILL No. 497

### DIGEST OF INTRODUCED BILL

**Citations Affected:** IC 25-26-19.

**Synopsis:** Home medical equipment services provider licensing. Requires a home medical equipment services provider who provides home medical equipment services in Indiana to be licensed by the Indiana board of pharmacy (board). Authorizes the board to conduct inspections, issue licenses, discipline providers for violations, and adopt rules to: (1) specify the medical equipment to be regulated; (2) set standards for the licensure of entities that provide home medical equipment services; (3) govern the safety and quality of home medical equipment services that are provided; (4) recognize certain individuals; and (5) set reasonable fees for the application issuance and renewal of a license.

**Effective:** July 1, 2003.

**Dillon**

January 23, 2003, read first time and referred to Committee on Health and Provider Services.

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First Regular Session 113th General Assembly (2003)

PRINTING CODE. Amendments: Whenever an existing statute (or a section of the Indiana Constitution) is being amended, the text of the existing provision will appear in this style type, additions will appear in **this style type**, and deletions will appear in ~~this style type~~.

Additions: Whenever a new statutory provision is being enacted (or a new constitutional provision adopted), the text of the new provision will appear in **this style type**. Also, the word **NEW** will appear in that style type in the introductory clause of each SECTION that adds a new provision to the Indiana Code or the Indiana Constitution.

Conflict reconciliation: Text in a statute in *this style type* or ~~this style type~~ reconciles conflicts between statutes enacted by the 2002 Regular or Special Session of the General Assembly.

## SENATE BILL No. 497

A BILL FOR AN ACT to amend the Indiana Code concerning professions and occupations.

*Be it enacted by the General Assembly of the State of Indiana:*

1 SECTION 1. IC 25-26-19 IS ADDED TO THE INDIANA CODE  
2 AS A **NEW** CHAPTER TO READ AS FOLLOWS [EFFECTIVE  
3 JULY 1, 2003]:

4 **Chapter 19. Home Medical Equipment Services Providers**

5 **Sec. 1. For purposes of this chapter, the following definitions**  
6 **apply:**

7 (1) "Board" refers to the Indiana board of pharmacy  
8 established by IC 25-26-13-3.

9 (2) "Bureau" refers to the health professions bureau  
10 established by IC 25-1-5-3.

11 (3) "Home medical equipment" means technologically  
12 sophisticated medical devices that may be used in a residence,  
13 including the following:

14 (A) Oxygen and oxygen delivery systems.

15 (B) Ventilators.

16 (C) Respiratory disease management devices.

17 (D) Continuous positive airway pressure (CPAP) devices.



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- 1 (E) Electronic and computerized wheelchairs and seating
- 2 systems.
- 3 (F) Apnea monitors.
- 4 (G) Transcutaneous electrical nerve stimulator (TENS)
- 5 units.
- 6 (H) Low air loss cutaneous pressure management devices.
- 7 (I) Sequential compression devices.
- 8 (J) Feeding pumps.
- 9 (K) Home phototherapy devices.
- 10 (L) Infusion delivery devices.
- 11 (M) Distribution of medical gases to end users for human
- 12 consumption.
- 13 (N) Wheel chairs.
- 14 (O) Hospital beds.
- 15 (P) Nebulizers.
- 16 (Q) Other similar equipment determined by the board in
- 17 rules adopted under IC 4-22-2.
- 18 (4) "Home medical equipment services" means the:
  - 19 (A) sale;
  - 20 (B) rental;
  - 21 (C) delivery;
  - 22 (D) installation;
  - 23 (E) maintenance or replacement; or
  - 24 (F) instruction in the use;
- 25 of medical equipment used by an individual that allows the
- 26 individual to reside in a noninstitutional environment.
- 27 (5) "Home medical equipment services provider" means a
- 28 person engaged in the business of providing home medical
- 29 equipment services to an unrelated individual in the
- 30 individual's residence.
- 31 Sec. 2. (a) This chapter does not apply to the following:
  - 32 (1) Home health agencies (as defined in IC 16-27-1-2) that do
  - 33 not sell, lease, or rent home medical equipment.
  - 34 (2) Hospitals (as described in IC 16-21-2) that:
    - 35 (A) provide home medical equipment services only as an
    - 36 integral part of patient care; and
    - 37 (B) do not provide home medical equipment services or
    - 38 care through a separate business entity.
  - 39 (3) Manufacturers and wholesale distributors that do not sell
  - 40 or rent directly to the consumer.
  - 41 (4) Except as provided under subsection (b), practitioners (as
  - 42 defined in IC 25-1-11-2) that do not sell or rent home medical

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equipment.

(5) Veterinarians licensed under IC 15-5-1.1.

(6) Hospice programs (as defined in IC 16-25-1.1-4) that do not sell or rent home medical equipment.

(7) Health facilities licensed under IC 16-28 that do not sell or rent home medical equipment.

(b) A pharmacist licensed in Indiana or a pharmacy that sells or rents home medical equipment does not need to obtain a license under this chapter. However, the pharmacist or pharmacy is subject to the provisions of this chapter.

Sec. 3. (a) A person seeking to provide home medical equipment services in Indiana shall apply to the board for a license in the manner prescribed by the board.

(b) A home medical equipment services provider shall do the following:

(1) Comply with federal and state law and regulatory requirements for home medical equipment services.

(2) Maintain a physical facility and medical equipment inventory in the state on a site zoned for commercial use.

(3) Purchase and maintain product liability insurance and professional liability insurance and maintain proof of this coverage.

(4) Establish procedures to ensure that all personnel engaged in:

(A) the delivery;

(B) the orientation of a patient in the use of the equipment;

(C) reimbursement assistance;

(D) maintenance;

(E) repair;

(F) cleaning and inventory control of home medical equipment; and

(G) the administration of home medical equipment services;

receive annual continuing education established by the board.

(5) Maintain clinical records on a customer receiving home medical equipment services.

(6) Establish medical equipment maintenance and personnel policies.

(7) Provide emergency maintenance services for twenty-four (24) hours a day, seven (7) days a week.

(8) Comply with any rules adopted by the board under this chapter.

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1       **Sec. 4. (a) The board may adopt rules under IC 4-22-2 to do the**  
 2 **following:**

3       **(1) Specify the medical equipment to be regulated under this**  
 4 **chapter.**

5       **(2) Set standards for the licensure of entities that provide**  
 6 **home medical equipment services.**

7       **(3) Govern the safety and quality of home medical equipment**  
 8 **services that are provided.**

9       **(4) Recognize accreditation bodies under section 6 of this**  
 10 **chapter.**

11       **(5) Set reasonable fees for the application, issuance, and**  
 12 **renewal of a license under this chapter and set any other fees**  
 13 **permitted under IC 25-1-8.**

14       **(b) The board may consult with individuals engaged in the home**  
 15 **medical equipment services business to advise the board on the**  
 16 **formulation of rules under subsection (a). The individuals may not**  
 17 **be compensated or reimbursed for mileage by the board.**

18       **Sec. 5. (a) Except as provided in section 6 of this chapter, a**  
 19 **home medical equipment services provider must be licensed by the**  
 20 **board before the provider may provide home medical equipment**  
 21 **services. If a home medical equipment services provider provides**  
 22 **home medical equipment services from more than one (1) location**  
 23 **in the state, each location must obtain a license under this chapter.**

24       **(b) An applicant shall submit the application to the board on a**  
 25 **form adopted by the board. The nonrefundable application fee set**  
 26 **by the board must be submitted with the application. The fee may**  
 27 **be used to cover the board's costs of reviewing and inspecting**  
 28 **applicants and issuing a license under this chapter.**

29       **(c) If the board determines that the applicant:**

30       **(1) meets the standards set forth by the board; and**

31       **(2) has satisfied the requirements under this chapter and any**  
 32 **requirements established by the board by rule;**

33 **the board shall notify the applicant in writing that the license is**  
 34 **being issued to the applicant. The license is effective upon the**  
 35 **applicant's receipt of the written notification.**

36       **(d) A license issued under this chapter is effective for not longer**  
 37 **than two (2) years, on a date determined by the board.**

38       **(e) The board may renew a license for two (2) year terms.**

39       **Sec. 6. (a) An applicant for a license may submit documents that**  
 40 **show the applicant's accreditation through a national organization**  
 41 **recognized by the board.**

42       **(b) The board shall issue a temporary license to an applicant**

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under subsection (a) when the board:

- (1) receives a copy of a valid accreditation letter from a national organization that the board has recognized by rule under section 4(4) of this chapter; and
- (2) has conducted an inspection under section 7 of this chapter.

**Sec. 7. (a)** The board may inspect the operations and facilities of any applicant for a license under this chapter to determine whether the applicant should be granted a license.

**(b)** The board may conduct random inspections at any time for the following reasons:

- (1) To ensure the integrity and effectiveness of the licensing process.
- (2) To investigate a consumer complaint or a complaint by a qualified source as identified by the board.

**(c)** The board shall send the facility a report of the board's findings after the board completes an investigation under this section.

**(d)** A provider that disputes the report in subsection (c) may file an appeal with the board not more than thirty (30) days after receipt of the report. The board shall review the inspection report and, if the provider requests, conduct a new inspection.

**(e)** The board shall employ qualified inspectors to investigate complaints and conduct inspections. Investigators may review and audit records pursuant to an investigation or inspection during the inspected facility's normal business hours at the place of business of the provider being investigated.

**(f)** The board and the board's employees may not disclose confidential information obtained during an investigation except during a disciplinary hearing held under section 8 of this chapter or under a court order.

**Sec. 8.** The board may impose discipline under IC 25-1-9 on the holder of a license after a hearing or for any of the following reasons:

- (1) Violation of this chapter or violation of a rule established by the board.
- (2) Violation of a board order.
- (3) Failure to meet the standards set forth in section 3(b) of this chapter.
- (4) The conviction or plea of guilty in a felony or misdemeanor that involves dishonesty or that is directly related to providing medical equipment.

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(5) Negligence or gross misconduct in providing home medical equipment services.

(6) The aid, assistance, or willful allowance of another person in violating any provision under this chapter or rule adopted by the board.

(7) Failure to provide within sixty (60) days information in response to a written request from the board.

(8) The engagement in conduct that is likely to deceive, defraud, or harm the public.

(9) Denial, revocation, suspension, or restriction of a license in another state or jurisdiction to provide home medical equipment services for any reason other than the failure to renew the license.

(10) The receipt of a fee, commission, rebate, or other form of compensation for services not rendered.

(11) Knowingly making or filing false records, reports, or billings in the course of providing home medical equipment services, including false records, reports, or billings prepared for or submitted to state or federal agencies or departments.

(12) Failure to comply with federal rules issued under the federal Medicare program (42 U.S.C. 1395 et seq.) relating to operations, financial transactions, and general business practices of home medical services providers.

**Sec. 9. (a)** A person engaging in the business of home medical equipment services that knowingly provides home medical equipment services without a license issued under this chapter commits a Class A misdemeanor.

**(b)** Each day a violation continues constitutes a separate offense.

**(c)** In addition, the board may, in the name of the state, through the attorney general, apply in any court to enjoin a person from providing home medical equipment services in violation of this chapter.

**SECTION 2. [EFFECTIVE JULY 1, 2003] (a)** As used in this SECTION, "home medical equipment services provider" means a person engaged in the business of providing home medical equipment services to an unrelated individual in the individual's residence.

**(b)** A home medical equipment services provider engaged in the home medical equipment business on June 30, 2003, and through June 30, 2004, is subject to inspection by the board for compliance with the standards set forth in IC 25-26-19, as added by this act.

**(c)** If, upon the initial inspection under subsection (b), a home

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1 medical equipment services provider who is accredited by a  
2 national organization:

3 (1) passes the inspection, the board shall issue the home  
4 medical equipment services provider a license; or

5 (2) does not meet the inspection requirements, the home  
6 medical equipment services provider shall be issued a  
7 temporary license for a time period of twelve (12) months.

8 (d) When the board issues a temporary license under subsection  
9 (c)(2), the board shall provide the home medical equipment  
10 services provider in writing a list of the areas of noncompliance.

11 (e) After the twelve (12) month period described in subsection  
12 (c)(2), the board shall conduct an inspection to determine whether  
13 the home medical equipment services provider is in compliance  
14 with the standards set forth in IC 25-26-19, as added by this act. If  
15 the board determines that the home medical equipment services  
16 provider does meet the standards, the board shall issue the  
17 provider a license. If the board determines that the home medical  
18 equipment services provider is not in compliance, the board shall  
19 notify the home medical equipment services provider in writing  
20 that the board is denying the provider a license.

21 (f) This SECTION expires December 31, 2006.

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